K062426

DEC 15 2006

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy Orthopaedics, Inc. P.O. Box 988 700 Orthopaedic Drive Warsaw, IN 46581-0988
510(k) CONTACT:	Anne M. Schuler Sr. Regulatory Affairs Associate
DATE PREPARED:	August 17, 2006
TRADE NAME:	DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners
COMMON NAME:	Acetabular Cup Liner
CLASSIFICATION:	Hip joint metal/metal semi-constrained with an uncemented acetabular component prosthesis (per 21 CFR 888.3330), Class III Device
DEVICE PRODUCT CODE:	87 KWA
SUBSTANTIALLY EQUIVALENT DEVICE(S):	DePuy Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners (K003523, cleared December 13, 2000) DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners (K002883, cleared Ocotober 13, 2000) DePuy ASR Modular Acetabular Cup System (K040627, cleared August 5, 2005)

DEVICE INFORMATION:

A. DEVICE DESCRIPTION

The Pinnacle Metal-On-Metal (MOM) Acetabular Cup Liner is a metal liner that is intended for use with Pinnacle Acetabular Shells that have been cleared previously. The liners currently are offered with inner diameters (ID) of 28-36mm, this modification is to add 40 and 44mm Ids and to add a 36mm liner with a outer diameter (OD) of 50mm. The liners are offered in a neutral style only. The subject Pinnacle MOM liner is mechanically locked with the shell via a taper junction which is identical to the taper junction used for the cleared 28 and 36mm liners and articulates with previously cleared M-Spec metal prosthetic femoral heads.

B. INTENDED USE AND INDICATIONS

Intended Use

The subject Pinnacle Metal-On-Metal Liners are intended to be used with the DePuy Pinnacle metal acetabular shells to resurface the acetabular socket in cementless total hip arthroplasty.

Indications

The Pinnacle Metal-On-Metal Acetabular Cup Liners are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle Metal-On-Metal Acetabular Cup Liners are intended for use with DePuyPinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

C. BASIS OF SUBSTANTIAL EQUIVALENCE:

The modified Pinnacle Metal-On-Metal Acetabular Cup Liners have the same intended use, indications, manufacturing method, sterilization and packaging as the Pinnacle 36mm and 28mm Acetabular Liners cleared in K003523 and K002883 and the same intended use and indications as the ASR Modular Acetabular Cup System cleared in K040627. The design of the modified Pinnacle Metal-On-Metal Acetabular Cup Liners is similar to the design of the previously cleared Pinnacle Metal-On-Metal liners. The modified liners are offered in a range of sizes (inner and outer diameters) that fall within the range of sizes previously cleared for the ASR Modular Acetabular Cup System. Based on similarities in design, intended use, indications, manufacturing methods, sterilization and packaging DePuy believes that the Pinnacle Metal-On-Metal Acetabular Cup Liners are substantially equivalent to the previously cleared Pinnacle 36 and 28mm metal Acetabular Liners.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics Inc.
% Ms. Kathy Harris
Director of Regulatory Affairs
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

DEC 15 2006

Re: K062426
Trade/Device Name: DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis
Regulatory Class: Class III
Product Code: KWA
Dated: December 1, 2006
Received: December 4, 2006

Dear Ms. Harris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

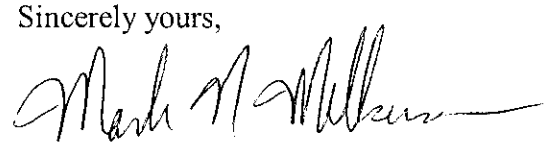
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062426
Device Name: DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

Indications for Use:
The Pinnacle Metal-On-Metal Acetabular Cup Liners are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

Prescription Use XX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062426